

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Shou TAKASHIMA et al.

Group Art Unit : 1652

Appl. No. : 10/501,930

(U.S. National Stage of PCT/JP03/00883)

Examiner : Ganapathiram RAGHU

I.A. Filed : January 30, 2003

Confirmation No. : 2173

For : SUGAR CHAIN SYNTHETASES

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop **AMENDMENT**  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

This is in response to the requirement for restriction under 35 U.S.C. 121 and 372 mailed from the U.S. Patent and Trademark Office on April 24, 2006, which sets a one-month shortened statutory period for response, ending May 24, 2006.

Applicants note that this response is being filed by the initial due date for response whereby an extension of time and the government fee associated therewith should not be necessary for maintaining the pendency of the application. However, if any extension of time is required to maintain the pendency of this application, this is an express request for any required extension of time and authorization to charge any necessary fee to Deposit Account No. 19-0089.

**RESTRICTION**

The Examiner has determined that two main Groups of inventions are contained in this application, namely:

- I. Claims 1-15, allegedly drawn to polypeptide with SEQ ID NO: 1 or SEQ ID NO: 3 with O-glycan  $\alpha$ 2,8-sialyltransferase activity, encoded by the polynucleotide of SEQ ID NO: 2 or SEQ ID NO: 4, vectors, host cells and the method of making said polypeptides; and
- II. Claims 16-30, allegedly drawn to polypeptide with SEQ ID NO: 5 or SEQ ID NO: 7 with  $\beta$ -galactoside  $\alpha$ 2,6-sialyltransferase activity, encoded by the polynucleotide of SEQ ID NO: 6 or SEQ ID NO: 8, vectors, host cells and the method of making said polypeptides.

The Examiner then proceeds to state that Groups I and II each contain patentably distinct species therein. These allegedly patentably distinct species are the specific polypeptide sequences recited in the claims, and the Examiner asserts that Applicant is required to elect a single species for prosecution.

**ELECTION**

In order to be responsive to the requirement for restriction, Applicants elect the invention set forth in Group I, claims 1-15, with traverse. Applicants further elect the polypeptide of SEQ ID NO: 1 and the corresponding polynucleotide of SEQ ID NO: 2, with traverse.

For the reasons set forth below, Applicants respectfully submit that the restriction requirement is improper, and should be withdrawn, whereby an action on the merits of all of the pending claims is warranted.

**TRAVERSE**

The requirement contends that the inventions lack the same or corresponding special technical features. However, Applicants note that 37 C.F.R. § 1.475(a) sets forth the definition of the requirement for unity of invention, and indicates that unity of invention must be satisfied, where a group of inventions is claimed, in order to have the right to include multiple inventions in a single application. In particular, 1.475(a) states that a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. In this regard, it is stated that:

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Applicants respectfully note that 37 C.F.R. § 1.475(b) permits the presence of a number of categories of invention to be compliant with unity of invention. For example, unity of invention can be present between a protein and a process of use thereof, or between proteins exhibiting the same activity yet different amino acid sequences. Applicants respectfully submit that unity of invention is present in this application.

Still further, Applicants respectfully submit that the same claim in Group I include O-glycan  $\alpha$ -2,8-sialyltransferase. The Office has not provided any

showing that *all* of the claim subject matter of Group I should not be considered together under the unity of invention rule. While an unsupported statement that the different claims within that Group are directed to different sequences having different structures, and thus are "distinct," may be sufficient in an application filed under 35 U.S.C. § 111 to support a Restriction Requirement, it is *insufficient* under unity of invention rules. Applicants submit that these claims should be examined together.

In view of the foregoing, it is respectfully requested that the Examiner reconsider the requirement for restriction, and withdraw the same so as to give an examination on the merits on all of the claims pending in this application.

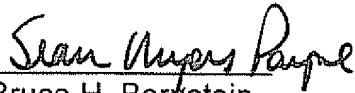
#### CONCLUSION

For the reasons discussed above, it is respectfully submitted that the requirement for restriction is improper, and the requirement should be withdrawn.

Withdrawal of the requirement for the restriction with examination of all pending claims is respectfully requested.

Favorable consideration with early allowance of all of the pending claims is most earnestly requested.

Respectfully Submitted,  
Shou TAKASHIMA et al.

  
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May 24, 2006  
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